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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,116	12/12/2003	Henryk Dudek	CIBT-P03-068	1883

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EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,116	DUDEK ET AL.	
	Examiner	Art Unit	
	Raymond J Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-35 and 39-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *25-35 and 39-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *12252004* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 25-35 AND 39-41 ARE PRESENTED FOR EXAMINATION

The originally filed application papers submitted on December 12, 2003 have been received and entered into the application. Accordingly, a "Substitute Specification for Publication" has been entered. These papers constitute a disclosure, a set of claims and an abstract of the disclosure. Amendments/alterations to the disclosure and claims have been made.

Claims have been Renumbered

Pursuant to 37 C.F.R. § 1.126, claims 1-14 have been renumbered as 25-35 and 39-41, respectively. See "Numbering of Claims", *infra*.

Informalities Noted

The present Office action is a Restriction/Election Requirement. However, the Examiner has noted several informalities in the papers as originally filed. In response to this Office action, in order to expedite prosecution of the application, Applicants are required to address the following matters in addition to complying with the Restriction Requirement set forth *infra*.

Numbering of Claims

37 CFR § 1.126 states:

"The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled the remaining claims must not be renumbered. When claims are added, they must be numbered by the applicant consecutively beginning with the number next following the highest numbered claim previously presented (whether entered or not). When the application is ready for allowance, the examiner, if necessary, will renumber the claims consecutively in the order in which they appear or in such order as may have been requested by applicant."

Applicants have not preserved the original numbering of claims (claims 1-38 originally filed and claims 39-41 added). For example, applicants have changed original (presently amended) claim "25" to "1" and have added new claim "12" after canceled claim "38".

In response to this Office action Applicants are required to submit a proper set of claims. The following is a suggested means to comply with the Examiner's request. It includes only a few portions of the claim set so as to exemplify the necessary format. Applicants should also note 37 CFR § 1.121(c) respecting the required use of claim identifiers, i.e., none of the claims presented by Applicants include claim identifiers.

"We claim:

Claims 1-24 (Canceled).

25. (Currently amended) A method for ~~inhibiting an altered growth state of~~ agonizing smoothened activity in a cell ~~having a *ptc* loss of function phenotype, *hedgehog* gain of function phenotype, or a *smoothened* gain of function phenotype~~, comprising contacting the cell with a composition including at least one cAMP ~~agonist~~ antagonist.

...

Claims 36-38 (Canceled).

Claim 39. (New) A method for promoting growth or differentiation of a neuronal cell, comprising treating the cell with a cAMP antagonist.

...".

Declaration

It is noted that the preliminary amendments made to the specification and claims are not referred to in the Declaration, i.e., the preliminary amendments were presented on December 12, 2003 while the declaration was executed on January 4, 2000 and on December 27, 1999.

A new Declaration indicating that Applicants have "reviewed and understand" the subject matter of the preliminary amendment filed December 12, 2003 should be submitted.

Support for Claimed Subject Matter

Applicants are required to point out the specific page and line of the present specification where support (verbatim support is not necessary, only that the concept be present) for the subject matter added to the claims by the Preliminary Amendment may be found, i.e., "agonizing smoothened activity in a cell" by "contacting the cell with a composition including at least one cAMP antagonist (original claim 25) and for the subject matter of each of claims 39-41 (originally numbered).

Also, Applicants are required to point out the specific page and line of the present specification where support may be found for the subject matter of claims 29 and 30 (originally numbered).

Current Status of Related Applications

Applicants should update the status, i.e., indicate the current patent number, of parent application SNs. 09/867,311 and 09/417,564 as set forth at page 1 of the specification, lines 1-2 under the heading "Cross-reference to Related Applications".

Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 40, drawn to a method for treating or preventing stroke comprising administering a composition including a cAMP antagonist to a patient, classified in class 514, various subclasses, depending on the specific cAMP antagonist considered.

II. Claim 41, drawn to a method for treating or preventing peripheral neuropathy comprising administering a composition including a cAMP antagonist to a patient, classified in class 514, various subclasses, depending on the specific cAMP antagonist considered.

Linking Claims

Claims 25-34, 35 (to the extent that the therapeutic or cosmetic application is the regulation of neural tissue) and 39 link the inventions of Groups I and II. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, i.e., claims 25-34, 35 (to the extent that the therapeutic or cosmetic application is the regulation of neural tissue) and 39. Upon allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicants are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is

withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Patentably Distinct Species

Claim 35 is generic to a plurality of disclosed patentably distinct species comprising:

(i) bone and cartilage formation and repair;

(ii) regulation of spermatogenesis;

(iii) regulation of smooth muscle;

(iv) regulation of lung, liver, and other organs arising from the primative gut;

(v) regulation of hematopoietic function; and

(vi) regulation of skin and hair growth.

Election Options

Applicants are required under 35 U.S.C. 121 to elect a single invention from the group consisting of Group I, Group II, species (i), species (ii), species (iii), species (iv), species (v) or species (vi), as set forth *supra*, even though this requirement is traversed.

Should applicants elect any one of species (i), species (ii), species (iii), species (iv), species (v) or species (vi), and traverse on the ground that the species are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The Grouped Inventions are Distinct

Each of the above Group I, Group II, species (i), species (ii), species (iii), species (iv), species (v) or species (vi) are unrelated. The unrelated nature of inventions can be established if it can be shown that the inventions not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as being capable of use together, i.e., each invention is directed to a separate therapeutic objective that is to be achieved through separate instances of administration of a cAMP antagonist, and each of the inventions has a different function and/or effect, i.e., the therapeutic objective to be attained through the practice of each invention is different.

Each of the above delineated diseases/conditions/therapeutic objectives represents a patentably distinct invention because, notwithstanding that applicants may have discovered a common underlying feature, i.e., *smoothened* activity, each disease/condition/therapeutic objective involves different considerations pertaining to etiology, diagnosis, pathophysiological manifestations and treatment protocols. A reference which anticipates one of the above inventions would neither anticipate nor make obvious any of the other inventions. One skilled in the art could readily practice the invention directed to any one of the above inventions without infringing and/or practicing the inventions of any of the other inventions and each of the above delineated inventions is fully capable of supporting a separate patent.

Further, because of the distinct and independent nature of the claimed inventions, a simultaneous search for all in both patent and non-patent data bases and evaluation of the claims

under 35 U.S.C. §§ 101, 102, 103 and/or 112 would impose a serious burden on the Examiner in conducting a proper examination of the present application.

Accordingly, the present requirement for an election of a single invention is proper for examination purposes.

Applicants are advised that a reply to this requirement must include an identification of the invention that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional inventions which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicants must indicate which are readable upon the elected invention.

A telephone call was made to the Offices of Ropes & Gray LLP on December 23, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

December 27, 2004